

For Consulting Center Use Only:

Date Received: _____

Assigned to: _____

Date Assigned: _____

Assigned by: _____

Completed date: _____

Reviewer Initials: _____

Supervisory Concurrence: _____

Intercenter Request for Consultative or Collaborative Review Form

To (Consulting Center):

Center:

Division:

Mail Code: HF

Consulting Reviewer Name:

Building/Room #:

Phone #:

Fax #:

Email Address:

RPM/CSO Name and Mail Code:

From (Originating Center):

Center:

Division:

Mail Code: HF

Requesting Reviewer Name:

Building/Room #:

Phone#:

Fax #:

Email Address:

RPM/CSO Name and Mail Code:

Requesting Reviewer's Concurring

Supervisor's Name:

Receiving Division: If you have received this request in error, you must contact the request originator by phone immediately to alert the request originator to the error.

Date of Request:

Requested Completion Date:

Submission/Application Number:
(Not Barcode Number)

Submission Type:
(510(k), PMA, NDA, BLA, IND, IDE, etc.)

Type of Product: .. Drug-device combination .. Drug-biologic combination .. Device-biologic combination
 .. Drug-device-biologic combination .. Not a combination product

Submission Receipt Date:

Official Submission Due Date:

Name of Product:

Name of Firm:

Intended Use:

Brief Description of Documents Being Provided (e.g., clinical data -- include submission dates if appropriate):

Documents to be returned to Requesting Reviewer? ☐ Yes ☐ No

Complete description of the request. Include history and specific issues, (e.g., risks, concerns), if any, and specific question(s) to be answered by the consulted reviewer. The consulted reviewer should contact the request originator if questions/concerns are not clear. Attach extra sheet(s) if necessary:

Type of Request: ☐ Consultative Review ☐ Collaborative Review